Psychological preparation and postoperative outcomes for adults undergoing surgery under general anaesthesia (Protocol)

Powell R, Bruce J, Johnston M, Vögele C, Scott N, Shehmar M, Roberts T

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TABLE OF CONTENTS

[Intervention Protocol]

Psychological preparation and postoperative outcomes for adults undergoing surgery under general anaesthesia

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Editorial group: Cochrane Anaesthesia Group.
Publication status and date: New, published in Issue 8, 2010.

Citation: Powell R, Bruce J, Johnston M, Vögele C, Scott N, Shehmar M, Roberts T. Psychological preparation and postoperative outcomes for adults undergoing surgery under general anaesthesia. *Cochrane Database of Systematic Reviews* 2010, Issue 8. Art. No.: CD008646. DOI: 10.1002/14651858.CD008646.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To review the effects of psychological preparation on postoperative outcomes in adults undergoing elective surgery under general anaesthetic.

BACKGROUND

Many people experience anxiety and negative cognitions when approaching surgery (Mathews 1981). There is good evidence that how people think and feel before surgery affects their outcomes after surgery. Anxiety, depression and catastrophizing have been found to predict postoperative pain (Arpino 2004; Granot 2005; Munafó 2001). Catastrophizing has been defined as 'an exaggerated negative orientation toward noxious stimuli' (Sullivan 1995).

A range of mechanisms exist by which psychological variables could affect recovery after surgery. First, negative emotions can enhance pain sensations (Rainville 2005). Second, cognitions and emotions influence behaviour (for example doing physiotherapy exercises, taking analgesics) and are likely to influence pain and return to usual activities. Third, stress has been linked to the slower healing of wounds through psychoneuroimmunological mechanisms (mechanisms whereby psychology interacts with the nervous and immune systems) (Marucha 1998).

Psychological preparation for surgery has been demonstrated to improve outcomes. In a systematic review and meta-analysis (Johnston 1993), psychological preparation was found to be beneficial for a range of outcome variables that included negative affect, pain, pain medication, length of hospital stay, behavioural recovery, clinical recovery, physiological indices and satisfaction.

Since the 1993 review (Johnston 1993) this research field has continued to develop. Standards of conducting randomized controlled trials have improved, technology has advanced to permit more detailed bibliographic searching and new studies testing psychological preparation procedures have been published. The present review will test, given modern review techniques, analysis methods and a larger research base, whether a) there is evidence for beneficial (or harmful) effects of psychological preparation for surgery, and b) which clinical, behavioural and psychological outcomes are improved (or worsened) following preparation. We will also review economic data, where available.

Description of the condition

Surgery is carried out for a range of health conditions either as a diagnostic or treatment intervention. While surgery may lead to health improvements, it also negatively impacts on a range of health outcomes including pain, activity limitations and anxiety, at least in the short term (Johnston 1980).
Elective surgery differs from emergency surgery in that patients have time to prepare themselves and to be prepared for surgery. Preparation for emergency surgery is much more difficult to provide in a controlled manner and the effectiveness of such interventions is likely to differ because of that difference in context. Thus, emergency surgery should be considered separately and we will only include participants undergoing elective surgery in this review.

Different psychological threats and coping mechanisms can be involved for the patient depending on whether procedures are undertaken using general anaesthetic or local anaesthetic. For example in some procedures that are performed under local anaesthetic the patients are required to be actively involved, and so effective preparation will have different components compared with preparation for a procedure where the patient is unconscious. Therefore, following Johnston and Vögele (Johnston 1993), we will only include procedures involving general anaesthetic.

Description of the intervention

Psychological preparation incorporates a range of strategies designed to influence how a person feels, thinks or acts (emotions, cognitions or behaviours). Johnston and Vögele (Johnston 1993) found the types of intervention that benefited patients, on at least one outcome, were procedural information, sensory information, behavioural instruction, cognitive intervention, relaxation, hypnosis and emotion-focused interventions.

Information

Procedural information describes the process the patient will undergo in terms of what will happen, when it will happen and how it will happen.
Sensory information describes the experiential aspects of the procedure, that is what it will feel like and any other relevant sensations (for example taste, smell).

Behavioural instruction

Behavioural instruction consists of telling patients what they should do to facilitate either the procedure or their recovery from the procedure (Mathews 1984). For example a patient could be told how to use equipment, such as a patient-controlled analgesia pump.

Cognitive behavioural interventions

Cognitive interventions aim to change how an individual thinks, especially about negative aspects of the procedure. Cognitive techniques include cognitive reframing and distraction.
Cognitive reframing involves developing a positive perspective on a negative thought, for example focusing on the number of people who do well after a surgical procedure rather than the number who fare badly.
Distraction leads to focusing thoughts on other things (and could include relaxation).

Relaxation techniques

These involve 'systematic instruction in physical and cognitive strategies to reduce sympathetic arousal, and to increase muscle

relaxation and a feeling of calm' (Michie 2008). Relaxation techniques can be used before surgery to reduce tension and anxiety and include progressive muscle relaxation (where each muscle group is tensed and then relaxed), simple relaxation (each muscle group is relaxed in turn), breathing techniques (for example the practice of diaphragmatic breathing) and guided imagery (for example imagining a pleasant, relaxing environment).

Hypnosis

A range of procedures are used for hypnotic induction, including suggestions to relax. During hypnosis, 'one person (the subject) is guided by another (the hypnotist) to respond to suggestions for changes in subjective experience, alterations in perception, sensation, emotion, thought or behavior' (APA 2005).

Emotion-focused intervention

Interventions which involve the discussion of emotions (for example anxiety, depression) include the expression or disclosure of emotions that a patient has.

How the intervention might work

Studies have shown that psychological preparation for surgery can have a beneficial effect upon a range of postoperative outcomes (Johnston 1993). Likely mechanisms for these processes vary depending upon the intervention used.

Why it is important to do this review

Improving outcomes after surgery has a range of benefits both for the individual and for the healthcare service. Individuals will benefit from reduced pain and a quicker return to activity. Economic benefits include shorter stays in hospital, reduced use of pain medication and quicker return to work.

OBJECTIVES

To review the effects of psychological preparation on postoperative outcomes in adults undergoing elective surgery under general anaesthetic.

METHODS

Criteria for considering studies for this review

Types of studies

We will include both published and unpublished randomized controlled trials. We will exclude quasi-randomized trials. We will include, and narratively describe, cluster-randomized controlled trials but we will not include them in the meta-analyses.

Types of participants

We will include studies with adult participants (aged 16 years or older) undergoing elective surgery under general anaesthesia. Some surgical procedures are carried out under either general or local anaesthesia (for example inguinal hernia repair surgery). We will include studies containing a mixture of patients undergoing general and local anaesthesia but we will exclude studies where all patients have undergone local (or no) anaesthesia (with or without sedation).

We will include studies of people who have received premedicative sedative prior to general anaesthesia. Different issues are encountered with children undergoing surgery (for example their developmental stage) and different psychological techniques are used (Johnston 1993). Studies tend to focus either on adults or children. A Cochrane review on non-pharmacological interventions for assisting the induction of anaesthesia in children has recently been published (Yip 2009). We will exclude participants aged less than 16 years from this current review.

We will exclude studies focusing on patient groups with clinically diagnosed psychological morbidity. However, we will not exclude studies which include participants with mental disorders or subclinical symptoms co-existing with the condition that led to the operation.

Types of interventions

Psychological preparation, including:

1. procedural information;
2. sensory information;
3. behavioural instruction;
4. cognitive behavioural interventions;
5. relaxation techniques;
6. hypnosis;
7. emotion-focused intervention.

Other types of psychological preparation intervention may be identified during the course of the review.

Types of outcome measures

The outcome measures do not form part of the criteria for including studies in this review, to allow for studies that may identify unanticipated benefits (or harm) resulting from the interventions.

Primary outcomes

1. Postoperative pain
1a. Postoperative pain intensity: there are a range of well-used measures for pain and some studies report pain as an outcome using more than one measure. We will extract all reported pain outcomes from each study.
We will use the following hierarchy when deciding which pain measure to use in the meta-analysis:
i) the pre-specified pain outcome (if given);
ii) a visual analogue scale, from 0 to 100 (or 0 to 10);
iii) McGill Pain Questionnaire (MPQ) (Melzack 1975) intensity rating, Present Pain Intensity;
iv) other MPQ ratings i) Pain Rating Index (weighted or unweighted), ii) Number of Words Counted;
v) other pain intensity scale.
1b. Proportion of patients in pain postoperatively as defined by the authors of included studies.
2. Behavioural recovery (defined as: resumption of performance of tasks and activities).

Secondary outcomes

1. Negative affect: postintervention and postoperative
2. Resource use
a. Length of stay, in hospital, in postanaesthesia care unit.
b. Postsurgical analgesia use: proportion of patients requiring an unplanned analgesia intervention in the postanaesthesia care unit, within 24 hours, at any time in hospital, after discharge.
Other measures of analgesia use.
3. Physiological recovery: postoperative physiological indices, including immune function and wound healing
4. Patient satisfaction with treatment
For the outcomes of behavioural recovery and negative affect we will include only studies that use measures with published psychometric properties, including reliability and validity. We will record the timing of outcome assessment.
Other outcomes may be identified during the course of conducting the review.
We will extract economic data wherever sufficient details are provided.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, latest Issue); MEDLINE (Ovid SP) (1950 to date); EMBASE (Ovid SP) (1982 to date); PsycINFO (Ovid SP) (1982 to date); CINAHL (EBSCOhost) (1980 to date); DISSERTION ABSTRACTS and ISI Web of Science (1946 to date).
We will use the following subject search terms for searching the databases (see Appendix 1 for full details):
'psychological preparat*', education, information, instruction, cognitive interven*, 'cognitive behavio?ral therapy', 'cognitive therapy', 'behavio*ral therapy', hypnosis, relaxation, guided imagery,
surgery, operat*, surgical procedure, general an*esthetic,
elective surgery, cholecystectomy, hysterectomy, hernia repair, herniorrhaphy, hernioplasty, joint replacement surgery, arthroplasty.
We will combine our subject search terms with the Cochrane highly sensitive search strategy for identifying randomized controlled trials (RCTs) as suggested in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). We will adopt the search strategy for MEDLINE (see Appendix 1) in order to search in all other databases.

Searching other resources

We will search the reference and citation lists of relevant papers for additional sources and adjust our search terms if it is found to be necessary. We will contact the authors of relevant studies to identify unpublished studies and dissertations.
We will not limit the search by language or publication status. We will seek English translations of non-English studies that have the potential to be included.

Data collection and analysis

Selection of studies

One review author will check titles and abstracts of retrieved studies to exclude obviously irrelevant reports. A small, random sample will be double-checked by a second author. Where the title and abstract indicate that a paper has the potential to fit study criteria, copies of the trial will be independently assessed for inclusion by two authors. We will resolve any disagreements by discussion with a third author.

Data extraction and management

Two review authors will independently carry out data extraction using a data extraction form (see Appendix 2). We will resolve any disagreement by discussing the matter with a third author. We will extract the following data.

- Study participants: age, gender, total number of participants, location, setting, surgery type.
- Study methods: study design, study duration.
- Interventions: theoretical nature of intervention, number of intervention groups, specific intervention, intervention details (including delivery method), integrity of intervention, timing of

intervention, control groups, usual care description, adherence to intervention and control, attrition rate, loss to follow-up rate.

- Outcomes: outcomes and time points a) collected, and b) reported; outcome definition, author's definition of outcome; measurement tool details (including e.g. upper and lower limits, whether high or low score is good outcome).
- Results: number of participants allocated to each intervention group, missing participants, means, standard deviations, proportions, estimate of effect with confidence interval, P value, subgroup analysis (monitors and blunters (information seekers or avoiders, see Miller 1983) when appropriate.
- Study withdrawals or losses to follow up.
- Information on cost per outcome.
- Resource use.

If necessary, we will contact study authors for additional data.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias using the tool described in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). This tool requires the review authors to assess risk of bias in the following domains: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias (we particularly note potential for contamination between intervention groups). In addition, review authors will be explicitly asked to note whether the study used intention-to-treat analysis methods (Hollis 1999) (see Appendix 3 for table).

Studies with high or unclear risk of bias will be given reduced weight in the meta-analysis compared with studies at low risk of bias. We anticipate that meta-analysis will be restricted to studies at low (or lower) risk of bias, as per Section 8.8.3.1 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). We will conduct sensitivity analyses to determine whether excluding studies at a high risk of bias affects the results. We do not expect blinding of participants or personnel administering the intervention. This is because of the interactive nature of the interventions, but we will note if blinding has been attempted. We will record the adequacy of the blinding of outcome assessors (returning data by post will be deemed acceptable).

Measures of treatment effect

We will enter quantitative data into Cochrane RevMan 5.0 software and, where appropriate, the data will be statistically aggregated.

We will perform an initial, omnibus meta-analysis over all intervention types for each outcome type. We will carry out further meta-analyses where interventions are identified as belonging to the same category and where the same outcomes are assessed. Some interventions will include more than one intervention component. We will analyse studies in groups assessing the same intervention combinations to ensure that we compare comparable studies. Where surgical populations and timing of outcome measures differ, we will carry out subgroup analyses.

We will perform the meta-analysis according to the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008). For dichotomous variables, we will calculate the relative risks (RRs) with 95% confidence intervals (CI). For continuous data, we will calculate standardized mean differences (SMD) (or mean difference (MD), when applicable) with 95% CI. Where continuous and dichotomous outcomes are presented for the same outcome, odds ratios will be re-expressed as SMDs and combined using the generic inverse-variance method in RevMan 5.0.

Where it is not possible to pool data, or if summary measures are medians (range or interquartile range (IQR)), these will be presented in table format and results will be discussed narratively. Where data are appropriate for meta-analysis, we will summarize findings for each intervention in a 'Summary of findings' table (Appendix 4). The quality of the body of evidence for each intervention will be assessed using the GRADE approach, as described in Chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008).

Unit of analysis issues

Where repeated measurements of outcomes are taken postoperatively, the earliest measure will be used for the main meta-analysis. This is because, while the longest follow up is important for longer-term recovery, it is likely that most studies will include short-term outcome data but only a few will also include longer time frames. In the subgroup analyses which address time of outcome, studies will be grouped according to the time of outcome measurement.

Some trials may compare multiple intervention groups. Where each arm assesses a different intervention, the interventions will be analysed separately in the appropriate meta-analysis. If a study includes two control arms (for example standard care and attention control), groups will be combined to form a single 'control' arm. An analysis will be conducted to compare standard care control and attention control participants.

Where an intervention is complex, that is containing more than one intervention type, it will be included in each analysis with a subsequent sensitivity analysis excluding such studies.

Dealing with missing data

We will contact authors if any necessary data are missing. If the majority of studies in a meta-analysis have missing standard deviations we will not impute the standard deviations. If a small proportion of studies are missing standard deviations, we will impute values according to the recommendations of the Cochrane Handbook (Chapter 16) (Higgins 2008). We will only include studies

using intention-to-treat (available case analysis) in the meta-analysis.

Assessment of heterogeneity

We will consider and test heterogeneity between trials, where appropriate. To test for gross statistical heterogeneity between all trials, we will use Chi^2 tests for heterogeneity and quantify heterogeneity using the I^2 statistic (Higgins 2008). If heterogeneity exists, we will explore the data and test whether our planned subgroup analyses explain the heterogeneity. As we are using a random-effects model, the existence of heterogeneity will not affect the inclusion of studies.

Assessment of reporting biases

We do not plan to assess reporting biases because of the probable heterogenous nature of the studies and probable small number of studies appropriate for comparison using, for example, funnel plots.

Data synthesis

We will use a random-effects model because of expected heterogeneity in interventions and outcomes.

Subgroup analysis and investigation of heterogeneity

If sufficient trials of adequate size exist, the subgroup analyses to be considered include trials:
* addressing different surgical procedures;
* differing in timing of outcome measure (e.g. acute, subacute, chronic postoperative pain);
* of high methodological quality compared with trials of low methodological quality;
* using different measures to assess the same outcome;
* comparing people who respond differently to information (e.g. 'monitors' versus 'blunters' (information seekers or avoiders), see Miller 1983);
* differing in focus of intervention (e.g. general anaesthesia, the surgery, recovery or outcome after surgery);
* differing in focus of intervention (general versus procedure specific).

Sensitivity analysis

We will carry out analyses by including and excluding trials using multiple techniques within an intervention. Jüni, Altman and Egger (Jüni 2001) recommend consideration of the important quality components of a given meta-analysis when conducting sensitivity analyses. We will perform sensitivity analyses to evaluate the effect on the overall result of removing trials with low methodological quality (as identified using the Cochrane tool) (Appendix 2). Low methodological quality studies are those where: a) sequence generation or allocation concealment is unclear, b) there is no or unclear blinding of outcome assessors, c) incomplete outcome data are not adequately addressed (assessed as no or unclear), d) the study appears to be at risk of selective outcome reporting (no or unclear), d) the study appears to be at risk of other sources of bias (no or unclear).

ACKNOWLEDGEMENTS

We would like to thank Andrew Smith (content editor), Nathan Pace (statistical editor) Michael Wang, Allan Cyna (peer reviewers) and Lynda Lane (Cochrane Consumer Network representative) for their help and editorial advice during the preparation of this protocol.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy for MEDLINE (Ovid SP)

1. (prevent* adj3 (anxiety or stress or depression or catastrophizing or negative orientation or noxious stimuli or negative emotion*)).mp.
2. physiotherapy exercise*.ti,ab. or taking analgesic*.mp. or (Psychological adj3 preparation*).mp. or ((sensory or procedural) adj3 information).mp. or behavio?ral instruction*.mp. or ((emotion?focused or cognitive) adj3 intervention*).mp. or (relaxation or hypnosis).ti,ab. or (cognitive adj3 (reframing or distraction)).mp. or guided imagery.mp.
3. Patient Education as Topic/ or Behavior Therapy/ or Cognitive Therapy/ or Relaxation Therapy/ or Hypnosis, Anesthetic/ or Hypnosis/ or "Imagery (Psychotherapy)"/
4. 1 or 2 or 3
5. ((post?operative adj3 (outcome* or pain)) or post?surgical pain).mp. or (surgery or operat*).ti,ab. or surgical procedure*.mp.
6. Postoperative Care/ or exp Pain, Postoperative/ or Postoperative Complications/ or General Surgery/ or Cholecystectomy/ or Hysterectomy/ or Arthroplasty, Replacement/ or Arthroplasty/ or Anesthetics, General/ or Anesthesia, General/
7. (cholecystectom* or hysterectom* or (hernia adj5 repair*) or herniorrhaph* or hernioplasty or (joint replacement adj3 surgery) or arthroplasty).mp. or (general adj3 an?esth*).ti,ab.
8. 6 or 7 or 5
9. ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti.) not (animals not (humans and animals)).sh.

10. Economics/ or "Costs and Cost Analysis"/ or exp Cost-Benefit Analysis/ or (economic adj3 evaluation).ti,ab. or cost effectiveness analysis.mp. or cost utility analysis.mp. or Cost minimisation.mp. or "Cost Savings"/ or QALY.mp. or Quality-Adjusted Life Years/
11. (10 or 9) not (child not (child and adult)).sh.
12. 8 and 11 and 4

Appendix 2. Data extraction form

Study details	
Study ID:	
Authors & Year:	
Journal/Source:	
Volume/page numbers:	
Title:	
Study location and setting:	
Language:	
Reviewer:	Date of entry:
Participant characteristics	
Age (mean, median, range etc):	
Gender (no./%):	
Surgery type(s):	
% general anaesthetic:	
% sedative prior to anaesthetic	
No. eligible patients:	No. randomized:
No./% participants lost to follow-up:	
Interventions	
Control group	
Components:	
Administration (including when, duration, by whom, how, materials):	

(*Continued*)

Fidelity (integrity of intervention delivery, participant adherence, attrition rate):

Loss to follow-up:

Intervention 1:
Theoretical basis of intervention:

Components:

Administration (including when, duration, by whom, how, materials):

Fidelity (integrity of intervention delivery, participant adherence, attrition rate):
Procedure-specific/general?

Loss to follow-up:

Intervention 2:
Theoretical basis of intervention:

Components:

Administration (including when, duration, by whom, how, materials):

Fidelity (integrity of intervention delivery, participant adherence, attrition rate):
Procedure-specific/general?

Loss to follow-up:

Intervention 3:
Theoretical basis of intervention:

Components:

Administration (including when, duration, by whom, how, materials):

Fidelity (integrity of intervention delivery, participant adherence, attrition rate):
Procedure-specific/general?
Loss to follow-up:

Outcomes

Outcome 1: (outcome type (outcome definition & study authors' definition if different), timing):

Measurement tool (including upper/lower limits, whether high or low score desirable)

(*Continued*)

Published psychometrics for measurement tool? Y / N / N/A
Outcome 2: (outcome type (outcome definition & study authors' definition if different), timing): Measurement tool (including upper/lower limits, whether high or low score desirable) Published psychometrics for measurement tool? Y / N / N/A
Outcome 3: (outcome type (outcome definition & study authors' definition if different), timing): Measurement tool (including upper/lower limits, whether high or low score desirable) Published psychometrics for measurement tool? Y / N / N/A
Outcome 4: (outcome type (outcome definition & study authors' definition if different), timing): Measurement tool (including upper/lower limits, whether high or low score desirable) Published psychometrics for measurement tool? Y / N / N/A
Outcome 5: (outcome type (outcome definition & study authors' definition if different), timing): Measurement tool (including upper/lower limits, whether high or low score desirable) Published psychometrics for measurement tool? Y / N / N/A
Outcome 6 (outcome type (outcome definition & study authors' definition if different), timing): Measurement tool (including upper/lower limits, whether high or low score desirable) Published psychometrics for measurement tool? Y / N / N/A
Any outcomes collected but not reported? Yes / No If yes, give details:

Continuous data				
Outcome	*Intervention 1 (state)*		*Control*	
	N	Mean (SD)	N	Mean (SD)
1.				
2.				
3.				
4.				
5.				
6.				
Outcome	*Intervention 2 (state)*		*Control*	
	N	Mean (SD)	N	Mean (SD)
1.				
2.				
3.				
4.				
5.				
6.				
Outcome	*Intervention 3 (state)*		*Control*	
	N	Mean (SD)	N	Mean (SD)
1.				
2.				
3.				
4.				
5.				

(*Continued*)

6.				

Dichotomous data		
Outcome	*Intervention 1 (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome	*Control (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome
1.		
2.		
3.		
4.		
5.		
6.		
Outcome	*Intervention 2 (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome	*Control (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome
1.		
2.		
3.		
4.		
5.		
6.		
Outcome	*Intervention 3 (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome	*Control (n/N)* n = no. participants with the outcome N = no. participants at risk of outcome
1.		
2.		
3.		
4.		

(*Continued*)

5.		
6.		

Other outcome information: e.g. study's estimation of effect sizes with confidence intervals and P values, any subgroup analyses, comments on analyses (e.g. use of multi-level modelling/random-effects regression).
Information on cost per outcome: If any information is given on cost per outcome, detail below.
Information on resource use (if not already reported as an 'Outcome')

Other relevant information Indicate if any data were obtained from the primary author, if results estimated e.g. from graphs or calculated by you (give formula) - indicate any other methods of obtaining results other than reading in paper.
Any other comments - including writing actions e.g. contact with study authors.

Appendix 3. Risk of bias form

The Cochrane Collaboration's tool for assessing risk of bias (with additional intention-to-treat item).

Domain	Description	Review authors' judgment
Sequence generation		Was the allocation sequence adequately generated? YES / NO / UNCLEAR
Allocation concealment		Was allocation adequately concealed? YES / NO / UNCLEAR
Blinding of participants, personnel and outcome assessors *Outcome:* (a table line will be added for each addi-		Was knowledge of the allocated intervention adequately prevented during the study? YES / NO / UNCLEAR

(*Continued*)

tional outcome)		
Incomplete outcome data *Outcome:* (a table line will be added for each additional outcome)		Were incomplete outcome data adequately addressed? YES / NO / UNCLEAR
Selective outcome reporting		Are reports of the study free of suggestion of selective outcome reporting? YES / NO / UNCLEAR
Other sources of bias e.g. contamination, clustering?		Was the study apparently free of other problems that could put it at a high risk of bias? YES / NO / UNCLEAR
'Intention to treat'		Was the study analysed according to Intention to Treat? YES/NO/UNCLEAR

Appendix 4. Summary of findings table

Outcomes	Mean		Standardized Mean Difference (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
Pain						
Behavioural recovery						
Negative affect						
Postoperative analgesic use						
Postoperative length of stay						
Satisfaction with treatment.						

HISTORY

Protocol first published: Issue 8, 2010

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Marie Johnston (MJ), Rachael Powell (RP), Julie Bruce (JB)

Co-ordinating the review: RP

Undertaking manual searches: Research assistant (RA)

Screening search results: RA, RP

Organizing retrieval of papers: RA

Screening retrieved papers against inclusion criteria: RA, RP

Appraising quality of papers: RA, RP, JB, Manjeet Shehmar (MS), Claus Vögele (CV)

Abstracting data from papers: RA, RP, JB, MS, CV

Writing to authors of papers for additional information: RA

Obtaining and screening data on unpublished studies: RA, RP

Data management for the review: RA, RP, JB, Neil Scott (NS)

Entering data into Review Manager (RevMan 5.0): RA, RP

Analysis of RevMan statistical data: RP, JB, NS

Other statistical analysis not using RevMan: RP, JB, NS

Double entry of data: (data entered by person one: RA/RP; data entered by person two: RA/RP/JB/MS)

Interpretation of data: All

Statistical inferences: All

Writing the review: RP with support from all other authors

Securing funding for the review: RP with support from all other authors

Performing previous work that was the foundation of the present study: MJ, CV

Guarantor for the review (one author): RP

Person responsible for reading and checking review before submission: RP

DECLARATIONS OF INTEREST

Marie Johnston and Claus Vögele carried out a systematic review and meta-analysis in this area (Johnston 1993) but searching techniques have since become more sophisticated due to technological developments.

Rachael Powell designed a study, whilst she was a post-doctoral researcher at the University of Auckland, that would have been eligible for inclusion in this review had it been completed. However the study did not progress due to recruitment problems (very few data sets were completed and the study was halted).

All other authors: none known.